Medicaid and Health Choice Clinical Coverage Policy No.: 3H-1 Amended Date:

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To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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NC Medicaid Home Infusion Therapy

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1.0 Description of the Procedure, Product, or Service

The Home Infusion Therapy (HIT) program covers self-administered infusion therapy and enteral supplies provided to a NC Medicaid (Medicaid) or NC Health Choice (NCHC) beneficiary residing in a private residence or to a Medicaid beneficiary residing in an adult care home. Covered services include the following:

- a. Total parenteral nutrition (TPN);
- b. Enteral nutrition (EN);
- c. Intravenous chemotherapy;
- d. Intravenous antibiotic therapy; and
- e. Pain management therapy, including subcutaneous, epidural, intrathecal, and intravenous pain management therapy.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 - 1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
 - 2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in Section 3.0 of this policy.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

- a. Medicaid
 - None Apply.
- b. NCHC

None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- 1. that is unsafe, ineffective, or experimental or investigational.
- 2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

- 1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- 2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

2.3 Managed Care Participation

Beneficiaries participating in Community Care of North Carolina/Carolina ACCESS programs (CCNC/CA) shall gain access to home health services through their primary care physicians.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

HIT services are covered when all criteria in **Sections 3.0** are met in accordance with criteria for the specific therapy ordered. Please note the following program criteria:

- a. The service can be furnished safely in the living environment.
- b. The beneficiary's clinical status is stable as determined by the attending physician.
- c. The service is provided in the beneficiary's private residence or in an adult care home (such as a domiciliary care or family care home).
- d. The treatment is self-administered.

Note: "Self-administered" is defined as a beneficiary or an unpaid primary caregiver who is able and willing to administer the therapy following teaching and with monitoring.

e. The home environment is conducive to the provision of the HIT therapy, i.e., clean environment with electricity, water, telephone access, refrigeration, and physical space to support HIT supplies.

3.3 Medical Necessity Criteria

HIT services must be medically necessary for the treatment of a beneficiary's illness, injury, or medical condition as documented by the physician who orders the service. The beneficiary must be under the care of the referring physician.

3.4 Drug Therapies

Drug therapy is covered when all criteria specified in **Sections 3.0** and the criteria listed below are me:

- a. The treatment is self-administered.
- b. The beneficiary's medical condition supports the safe administration of the therapy in the home.
- c. The beneficiary has an available site for the administration of the therapy.
- d. The physician has determined that the need for HIT infusion of a drug is appropriate for at least one of the reasons stated below:
 - 1. HIT is more effective than oral or injectable administration.
 - 2. The medication is not available in an oral form.
 - 3. The medication cannot be tolerated orally.

Drug therapy services include equipment, supplies, delivery of these items, and any nursing services needed to teach, monitor, and assist the beneficiary. The drug is reimbursed separately through the Outpatient Pharmacy program as a prescription drug. The drug therapies covered by the program include the following:

- a. intravenous chemotherapy;
- b. intravenous antibiotic therapy; and
- c. pain management therapy, including subcutaneous, epidural, intrathecal, and intravenous pain management therapy.

3.5 Total Parenteral Nutrition Therapies

TPN is covered when all criteria specified in **Sections 3.0** and the criteria listed below are met:

- a. The beneficiary has a medical condition that prohibits adequate oral intake of nutrients, including the inability to ingest, tolerate and absorb sufficient oral nourishment to maintain or improve health status.
- b. The beneficiary has an available site for the administration of the therapy.

Nutrition therapy services include:

- 1. the rental or purchase of pumps used for TPN and the IV pole ordered by the physician:
- 2. formulae/solutions ordered by the physician;
- 3. medical supplies ordered by the physician; and
- 4. the cost of delivery of supplies and items to the beneficiary's residence.

Note: Nursing services are not covered. Refer to the Medicaid Home Infusion Therapy Fee Schedule at http://www2.ncdhhs.gov/dma/fee/HIT/hit0712.pdf for a list of covered formulae/solutions and medical supplies.

3.6 Enteral Nutrition Therapies

EN is covered when all criteria specified in **Sections 3.0** and the criteria listed below, are met.

- a. The beneficiary has a functioning gastrointestinal tract but with the inability to physically ingest or tolerate adequate oral intake of nutriments to maintain or improve health status.
- b. The beneficiary has an available site for the administration of the therapy.

Note: Oral nutrition and supplements are not covered under this policy.

Nutrition therapy services include:

- a. the rental or purchase of pumps used for EN and the IV pole ordered by the physician;
- b. formulae/solutions ordered by the physician;
- b. medical supplies ordered by the physician; and
- c. the cost of delivery of supplies and items to the beneficiary's residence.

Note: Nursing services are not covered. Refer to the Medicaid Home Infusion Therapy Fee Schedule athttp://www2.ncdhhs.gov/dma/fee/HIT/hit0712.pdf for a list of covered formulae/solutions and medical supplies.

3.7 Infusion Nursing Services

The infusion nursing services component of drug therapies includes:

- a. assessing the beneficiary for the appropriateness of HIT;
- b. monitoring the beneficiary;
- c. teaching the beneficiary and/or primary caregiver about the HIT administration;
- d. changing intravenous (IV) sites and dressings;
- e. drawing blood for laboratory analysis; and
- f. supervising the first dose as specified in **Subsection 7.2.1.1**.

3.8 Pharmacy Services

The pharmacy component of drug therapies includes:

- a. monitoring the drug therapy to ensure that the drugs and related fluids are dispensed according to the physician's plan of care (POC) and standards of practice;
- b. developing a medication history and beneficiary profile;
- c. consulting with physicians and nurses on the therapy;
- d. providing drug use evaluations;
- e. providing quality assurance; and
- f. procuring drugs and maintaining the inventory, reconstituting drugs, preparing dosage(s), labeling drugs, and delivering to a beneficiary's residence. The reimbursement for the drug is not included as a HIT service.

3.9 Medical Equipment and Supplies

Drug therapies include medical equipment and supplies needed for the therapy according to the POC and standards of practice.

3.10 Training

Training, including educational and counseling services, must be provided to ensure the safe and effective administration of HIT. The services are provided through a combination of verbal and written instructions.

3.8.1 Medicaid Additional Criteria Covered

None Apply.

3.8.2 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;
- b. the beneficiary does not meet the criteria listed in Section 3.0;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

HIT services are not covered when the eligibility criteria identified in **Section 2.0** and the criteria for coverage specified in **Section 3.0** are not met.

HIT services are not covered when:

- a. the service duplicates another provider's service;
- b. the service is experimental, investigational, or part of a clinical trial;
- c. the drug therapy is provided for services other than chemotherapy, antibiotic therapy or pain management; and/or
- d. the beneficiary is receiving Medicare-covered home health nursing services.

HIT drug therapy is not allowed for Medicaid beneficiaries receiving private duty nursing. The private duty nurse or the caregiver will provide the care needed if the beneficiary is receiving only EN or TPN. NCHC beneficiaries do not receive Private Duty Nursing services.

Nursing services for enteral and parenteral nutrition therapies are not covered.

Note: NC Medicaid's fiscal agent reimburses drug therapy at a per diem rate that includes both the nursing component and the drug therapy component. Reimbursement for EN and TPN services does not include a nursing charge.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 - 1. No services for long-term care.
 - 2. No nonemergency medical transportation.
 - 3. No EPSDT.
 - 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval for home infusion therapy services is required for Beneficiaries with Medicaid for Pregnant Women (MPW) coverage. Submit prior approval requests for home infusion therapy to NC Medicaid's designated fiscal agent on a Request for Prior Approval form (372-118).

5.1 **5.2** Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.1.2 Specific

None Apply.

5.2 Amount of Service

HIT services are limited to what is medically reasonable and necessary to treat the beneficiary's disease, injury, illness, or condition and what is ordered by the physician.

5.3 Physician's Order

The beneficiary's physician identifies the need for HIT and provides signed, written orders that detail the needed services. The order for services must clearly document medical necessity, the starting date for care, the expected duration of the therapy, and the amount and type(s) of services required. The orders must be on the appropriate form as indicated below:

- a. Drug therapies and TPN orders must be documented on the Plan of Care form such as CMS-485 or similar form.
- b. EN orders can be documented either on the Plan of Care form (CMS-485) or the Certificate of Medical Necessity/Prior Approval (CMN/PA) Form used by durable medical equipment (DME) providers.

Note: If the CMS-485 is not used, the following information must be documented in accordance with agency policy and all applicable state and federal licensure rules:

- a. Patient's name
- b. Birthdate
- c. Medicaid number
- d. Patient's address and telephone number
- e. Provider number
- f. Provider name, address, and telephone number
- g. Attending physician name, address, and telephone number
- h. ICD-10-CM and other pertinent diagnosis date.
- i. Objective information to substantiate medical necessity
- j. Physician signature and date

5.4 Beneficiary Assessment

After receiving the referral/order from the physician, the agency must assess the beneficiary to ensure that HIT services are appropriate and that the agency can provide all of the services needed. The HIT agency must assess the beneficiary, the beneficiary's environment, and availability of caregivers, if needed. The agency should not accept a referral if it cannot provide all components of the needed service either directly or through an arrangement. A registered nurse (RN) representing the HIT agency makes an initial visit to assess the beneficiary.

During the assessment, the RN must determine that:

- a. the therapy can be administered successfully and in accordance with the physician's orders:
- b. the beneficiary and/or responsible caregiver are motivated to use HIT, understand the purpose of the therapy, are capable of self-administration, are able to adhere to a disciplined medical regimen, and are realistic in coping with issues involved with treatment in the home:
- c. the condition of the beneficiary, the available support, and the beneficiary's home environment are conducive to safe and effective care; and
- d. other services that the beneficiary is receiving do not conflict with, interfere with, or duplicate HIT services.

5.5 Beneficiary/Caregiver Training

The HIT agency provides the necessary training to carry out the therapy according to the physician's orders. Responsibilities for training differ with each type of therapy.

5.5.1 Drug Therapy Training

The HIT RN ensures that the beneficiary and/or caregiver has received proper training. The pharmacist may also be involved in the training. The beneficiary/caregiver should understand the following:

a. how to administer the therapy;

- b. how to care for the supplies, equipment, and drugs;
- c. the responsibilities of the beneficiary/caregiver and the agency; and
- d. the symptoms and conditions that need immediate action and the actions required in each situation, including emergency procedures.

The agency must provide the beneficiary and/or caregiver with written instructions that include provisions for emergency situations and a telephone number to contact the agency 24 hours a day.

The HIT nurse should monitor the first dose given at home and provide any needed follow-up training and supervision as specified in **Subsection 7.2.1.1**.

5.5.2 Enteral Nutrition and Total Parenteral Nutrition Training

Because nursing services are not covered for EN and TPN therapy, a referral should be made for home health services if the beneficiary/caregiver requires intensive training for the administration of the therapy.

The HIT provider must make sure that the beneficiary and/or caregiver understands the following:

- a. how to care for supplies, equipment, and formulae; and
- b. the responsibilities of the agency and the responsibilities of the beneficiary/caregiver.

The agency must provide the beneficiary/caregiver with written instructions, including provisions for emergency situations and a telephone number to contact the agency 24 hours a day.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

The agency staff must be properly trained and capable of providing the needed services. Services requiring licensed personnel must be provided by staff members who are currently licensed by the appropriate North Carolina licensure board(s).

Outpatient pharmacy services must be provided by a registered pharmacist.

Infusion nursing services must be provided by a licensed nurse, in accordance with the North Carolina Nurse Practice Act, who is directly employed and/or contracted by the HIT agency.

- a. The staff member cannot be the beneficiary's spouse, child, parent, grandparent, grandchild, or sibling, or be a person with an equivalent step- or in-law relationship to the beneficiary.
- b. The agency must make services available 24 hours a day, seven days a week.

6.2 Provider Certifications

HIT services are provided by an agency licensed by the Division of Health Service Regulation (DHSR) as a home care agency and approved to provide infusion nursing services pursuant to 10A NCAC 13J (adopted by reference). Providers who meet the qualifications for participation shall be enrolled with the N.C. Medicaid program to provide this service.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

7.2 Monitoring Care

Monitoring responsibilities depend on the type of therapy (drug or nutrition) provided.

7.2.1 Drug Therapy Monitoring

The amount and type of monitoring must be appropriate for the drug administered, the individual beneficiary, and the success or effectiveness of the training provided. The beneficiary's physician and the HIT agency must ensure sufficient monitoring to protect the health and well-being of the beneficiary.

7.2.1.1 Administering the First Dose

The physician determines if the first dose is to be administered in the physician's office, hospital, or the beneficiary's home, including an adult care home. The HIT nurse must always monitor the administration of the first dose when administered in the beneficiary's home or an adult care home. The term "first dose" does not apply if the drug was previously administered by another route or an IV medication that the beneficiary has received in the past 60 calendar days.

7.2.1.2 Monitoring Subsequent Doses

Subsequent doses are monitored as needed to ensure quality care. The beneficiary's/caregiver's performance in administering the therapy should be monitored as needed and according to agency protocol.

7.2.1.3 Monitoring Amphotericin B

Nursing services for monitoring the administration of Amphotericin B may be billed separately from the HIT per diem for services that exceed two hours. The first two hours are included in the per diem.

7.2.1.4 Monitoring for Continuing Need and Appropriateness

Throughout the duration of the therapy, the HIT agency must review and monitor the administration of the drug to ensure that the need for treatment continues to meet the criteria for coverage listed in **Section 3.0**.

7.2.2 Enteral Nutrition and Total Parenteral Nutrition Monitoring

The HIT agency and the physician must ensure sufficient monitoring to protect a beneficiary's health and well-being. The physician may order other services, such as home health skilled nursing visits, if needed by the beneficiary receiving EN or TPN. HIT agency responsibilities for monitoring EN and TPN include ensuring provision of the supplies, equipment, and formulae, as well as documenting and reporting problems and concerns.

7.3 Coordinating Care

HIT services must be coordinated with other home care services to avoid duplication.

7.3.1 Home Health Services

7.3.1.1 Drug Therapies

Home health nursing services may be provided if unrelated to infusion therapy.

7.3.1.2 Enteral Nutrition or Total Parenteral Nutrition

HIT nursing services are not covered for beneficiaries receiving EN or TPN. The beneficiary must be referred for home health services when skilled nursing care (training or monitoring) is required.

7.3.2 Private Duty Nursing

- a. HIT drug therapy is not allowed for Medicaid beneficiaries receiving private duty nursing services.
- b. The private duty nurse or the caregiver will provide the care needed if the beneficiary is receiving only EN or TPN.
- c. NCHC beneficiaries do not receive Private Duty Nursing.

7.3.3 In-Home Care Services

Drug therapy, EN, and/or TPN may be provided for the beneficiary receiving inhome care services.

7.3.4 Community Alternatives Programs

If the beneficiary participates in a Community Alternatives Program (CAP), the case manager shall be contacted. CAP participants have a two-letter code in the CAP block of the MID card. CAP beneficiaries have a cost limit for Medicaid

home and community-based services that may affect their ability to receive HIT services.

7.3.5 Home Infusion Therapy Services in the Adult Care Home

The agency and the beneficiary's physician must coordinate the provision of HIT with the facility operator to ensure that the setting is appropriate and that there is adequate support to successfully administer the service as well as to provide for the health and safety of the beneficiary.

7.3.6 Medicare Part D

For medications covered under Medicare Part D, the HIT provider can bill Medicaid the applicable therapy code.

7.4 Providing Multiple Drug Therapies

If the beneficiary requires multiple drug therapies, the therapies must be provided by the same agency.

7.5 Drug and Nutrition Therapies Provided for the Same Beneficiary

The IV pole for the nutrition therapy cannot be billed if a beneficiary receives a nutrition therapy with a drug therapy.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1998

Revision Information:

Date	Section Revised	Change
09/01/2006	Section 1.0	Tocolytic therapy was added to the list of covered services.
12/01/2006	Section 2.6	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0, 4.0,	A note regarding EPSDT was added to these sections.
	and 5.0	
04/01/2007	Attachment A,	HCPCS procedure code E0781, erroneously omitted, was added.
	Section D	
04/01/2007	Sections 2.6, 3.0,	EPSDT information was revised to clarify exceptions to policy
	4.0, and 5.0	limitations for recipients under 21 years of age
08/01/2007	Section 5.1.5	Added a note that nursing services are not covered.
08/01/2007	Section 6.1	Changed the name of Division of Facility Services (DFS) to
		Division of Health Service Regulation (DHSR).
08/01/2007	Attachment A,	Deleted instructions regarding billing some codes in a specific
	letter C, #3	order.
08/01/2007	Attachment A,	Added a note that E0781 can only be billed with the RR modifier.
	letter D;	
0.5 /0.1 /0.01.0	Attachment C	71. 6
07/01/2010	Throughout	Policy Conversion: Implementation of Session law 2009-451,
		Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR
05/01/2012	Thurst also set	CHANGING MEDICAL POLICY."
05/01/2012	Throughout	Technical changes to merge Medicaid and NCHC current
06/15/2012	Header	coverage into one policy. Revised Date corrected to May 1, 2012
08/15/2012	Throughout	Replaced "recipient" with "beneficiary."
08/15/2012	Attachment	The following statements were deleted from the description as not
06/13/2012	A(C)(1), CPT	consistent with the HCPCS description and the NC DHHS
	code S9494.	Division of Medical Assistance Home Infusion Therapy fee
	code 33434.	schedule: "This code can only be used for antibiotic therapy.
		Antiviral and antifungal infusions are non-covered under the HIT
		Medicaid program".
10/01/2015	All Sections and	Updated policy template language and added ICD-10 codes to
10/01/2010	Attachments	comply with federally mandated 10/1/2015 implementation where
		applicable.
07/17/2018	Subsection 5.6.1	Policy posted to correct a graphical display glitch in the PDF. No
		change to policy or Amended Date.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan
		(PHP): for questions about benefits and services available on or
		after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and	Updated policy template language.
	Attachments	
01/06/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled

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Home Infusion Therapy	Clinical Coverage Policy No.: 3H-1
	Amended Date:

		in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/06/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
1/23/2023	Section 5.1 Prior Approval	Remove: 5.1 Prior Approval Prior approval for home infusion therapy services is required for Beneficiaries with Medicaid for Pregnant Women (MPW) coverage. Submit prior approval requests for home infusion therapy to NC Medicaid's designated fiscal agent on a Request for Prior Approval form (372-118). Return Numerical sequence: 5.1 to 5.2 for section-Prior Approval Requirements and continue as numbered for sections

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

1. Procedure Codes for Drug Therapies

HIT drug therapies are covered under a per diem charge. The per diem covers the therapy administration, supplies, and the nursing component (teaching, monitoring) of the therapy. HIT drug therapy must be billed using two HCPCS codes for each day of service to comply with national coding standards in accordance with HIPAA requirements. The applicable therapy code plus the nursing component code T1030 must be used for each day of therapy. An additional nursing charge is allowed with the administration of Amphotericin B. The code T1002 with the modifier SD is used if nursing services are required for **more than** 2 hours. The additional nursing charge is not allowed with any other infusion therapy.

The codes used to bill HIT drug therapies are listed in the chart below.

CPT	Description
Code	
S9494	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drug and nursing visits coded separately), per diem.
S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment

	(drug and nursing visits coded separately), per diem.	
S9325	Home infusion therapy, pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, (drug and nursing visits coded separately), per diem.	
T1030	Nursing care, in the home, by registered nurse, per diem.	
	This code must be billed with each therapy code billed. The reimbursement rate for the nursing component is prorated as a daily charge to cover the cost of nursing for the entire course of treatment.	
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drug and nursing visits coded separately), per diem.	
	This code can only be used for the drug therapy termination allowance. The service is covered when the therapy is discontinued or changed prior to the end of the prescribed treatment period. Medicaid will reimburse the termination allowance charge to cover each day for the lesser of the remainder of the treatment period or the cycle of delivery. Each day is billed as one unit with a maximum of seven days (7 units) for this code.	
T1002	RN Services, up to 15 minutes	
SD	The modifier SD denotes that the service was provided by a registered nurse with specialized, highly technical home infusion training. The modifier must be used when billing this code.	
	This code can be used for only RN monitoring (over 2 hours) for Amphotericin B infusion therapy.	

1. Additional Billing Information

Always bill the primary therapy code (S9494, S9329, or S9325) first.

Bill nursing services (T1030) after the related primary therapy code. Nursing services will not be paid unless the related primary therapy code has been paid for the same date of service.

The therapy and the nursing component are billed for each day in the prescribed course of treatment (1 unit equals one day).

When billing the termination allowance (S9379), bill the allowance after the related primary therapy code. The termination allowance will not be paid unless one of the therapy codes has been paid for a corresponding date of service.

When billing additional RN monitoring for the administration of Amphotericin B, three codes must be billed: S9494, antibiotic therapy, T1030 for the first two hours of nursing services covered with all therapies, and T1002 with the modifier SD in 15 min increments (1 unit equals 15 minutes).

Refer to **Attachment B**, **Billing for HIT Services**, for examples of billing for drug therapy services.

3. Billing for Enteral Nutrition Therapy and Total Parenteral Nutrition Therapy Nutrition therapy covers the equipment, supplies, and formulae/solutions ordered by the physician and provided according to standards of practice. The reimbursement for all components includes delivery to a beneficiary's residence. Each component is discussed below.

Formulae and solutions listed on the Home Infusion Therapy Fee Schedule are reimbursed either by the day or by the unit of service listed on the fee schedule.

Some medical supplies listed on the Medicaid Home Infusion Therapy Fee Schedule are provided as part of a kit.

Medical equipment, such as pumps used for EN and TPN and the IV pole, is reimbursed as a daily rental, a monthly rental, or a new or used purchase.

The item is **rented** if the physician documents that the anticipated need is six months or less.

The item may be **rented** or **purchased** if the physician documents that the anticipated need exceeds six months.

Rental of most equipment is covered as a <u>capped rental</u> item. The reimbursement is considered capped rental when the sum total of the rental payments equals the Medicaid allowable purchase price.

The appropriate modifier must be used when billing for medical equipment (HCPCS procedure codes B9002, B9004, B9006, E0781, and E0776).

NU	New purchase
UE	Used purchase
RR	Rental

Note: E0781 can only be billed with the RR modifier.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines. Multiple drug therapies administered concurrently are billed using the applicable drug infusion code with a modifier. The provider enters a primary therapy code plus the code for the nursing component (T1030) for each date of service. Each additional therapy is billed with the applicable code and modifier to indicate secondary and tertiary therapy.

The therapies can be billed in any order. The modifiers used to indicate second and third drug therapies are listed in the chart below.

Modifier	Description
SH	Indicates the second concurrently administered infusion therapy.
SJ	Indicates the third concurrently administered infusion therapy.

Refer to **Attachment B, Billing for HIT Services**, for examples of billing for multiple drug therapies.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Outpatient.

G. Co-payments

For Medicaid refer to Medicaid State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

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For NCHC refer to NCHC State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

Refer to Attachment C, Completing the CMS-1500 for HIT Services, for instructions to complete the CMS-1500 claim form with information specific to HIT billing.

General instructions for completing the CMS-1500 form can be found in Section 5 of the *Basic Medicaid and NCHC Billing Guide* on NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

Attachment B: Billing for HIT Services

1. Examples of Billing for HIT Drug Therapy

The nurse component HCPCS code must be billed with the therapy code for correct reimbursement of the per diem.

When billing for	Use these codes
Antibiotic Therapy	S9494 —Home infusion therapy, antibiotic <i>and</i>
_ '	T1030—Nursing care, in the home, by registered nurse, per diem
Chemotherapy	S9329—Home infusion therapy, chemotherapy infusion <i>and</i>
	T1030—Nursing care, in the home, by registered nurse, per diem
Pain Management	S9325—Home infusion therapy, pain management infusion <i>and</i>
Therapy	T1030—Nursing care, in the home, by registered nurse, per diem
Amphotericin B	S9494 —Home infusion therapy, antibiotic <i>and</i>
Therapy	T1030—Nursing care, in the home, by registered nurse, per diem <i>and</i>
Exceeding 2 hours of	T1002—RN Monitoring of Amphotericin B: Enter the number of 15-
nursing	minute units of monitoring in excess of two hours on the date of service.
	SD Modifier—Must be used with T1002.

2. Examples of Billing for Combination Therapies

Concurrent therapies can be billed in any order.

Concurrent	How to Bill
Therapies	
Two Concurrent	S9494 —Home infusion therapy, antibiotic <i>and</i>
Antibiotic Therapies	S9494 with modifier SH —Antibiotic therapy as the second billed
	therapy <i>and</i>
	T1030—Nursing care, in the home, by registered nurse, per diem
Antibiotic and	S9494 —Home infusion therapy, antibiotic <i>and</i>
Chemotherapy	S9329 with modifier SH —Chemotherapy as the second billed therapy
	and
	T1030—Nursing care, in the home, by registered nurse, per diem
Antibiotic and Pain	S9494 —Home infusion therapy, antibiotic <i>and</i>
Management	S9325 with modifier SH—Pain management infusion as the second
	billed therapy <i>and</i>
	T1030—Nursing care, in the home, by registered nurse, per diem
Chemotherapy and	S9329—Home infusion therapy, chemotherapy <i>and</i>
Pain Management	S9325 with modifier SH—Pain management infusion as the second
	billed therapy <i>and</i>
	T1030—Nursing care, in the home, by registered nurse, per diem
Antibiotic,	S9494 —Home infusion therapy, antibiotic <i>and</i>
Chemotherapy, and	S9329 with modifier SH—Chemotherapy as the second billed therapy
Pain Management	and
	S9325 with modifier SJ—Pain management infusion as the third billed
	therapy and
	T1030—Nursing care, in the home, by registered nurse, per diem

Attachment C: Completing the CMS-1500 for HIT Services

The following information specified below shall be used to complete the blocks that are specific to HIT billing. The program-specific information starts with block 24. Instructions for completing the CMS-1500 can be found in Section 5 of the *Basic Medicaid and NC Health Choice Billing Guide*. This document is posted on the NC Medicaid Web site https://medicaid.ncdhhs.gov/.

24A. DATE(S) OF SERVICE, From/To:

Drug Therapy Codes: Enter the date for the month that the course of treatment begins in the **From** block. Enter the last day of the course of treatment for the month in the **To** block.

When billing for a **second** therapy, the dates of service must be the same as the primary therapy. When billing for a **third** therapy, the dates of service must be the same as the primary and second therapy.

Nursing Services: Enter the same dates of service as listed for the related drug therapy.

RN Monitoring for Amphotericin B: Use a separate line for each day the monitoring is done. Enter the date of the monitoring in the **From** block. Enter the same date in the **To** block.

Termination Allowance for an Interrupted Course of Treatment: Enter the date of the last day of treatment in the **From** block. Enter the same date in the **To** block.

24B. PLACE OF SERVICE:

Enter 12 to show that the items/services were provided at the beneficiary's home.

24C. TYPE OF SERVICE:

Enter 15.

24D. PROCEDURES, SERVICES OR SUPPLIES:

Enter the appropriate HCPCS code.

For a second or third concurrent therapy, enter the appropriate modifier (second SH or third SJ) under MODIFIER.

For medical equipment HCPCS codes B9002, B9004, B9006, E0781, and E0776 enter one of the following under MODIFIER:

NU for new purchase

UE for used purchase

RR for rental

Note: E0781 can only be billed with the RR modifier.

24E. DIAGNOSIS CODE:

Leave blank.

Note: The diagnosis code must be entered in block 21. Enter the ICD-10-CM code for the principal diagnosis that corresponds to the service rendered. "V" codes are not acceptable.

24F. CHARGES

Enter the total charge for the items on the detail line.

24G. DAYS OR UNITS:

Enter the number of units billed on the detail line as indicated below.

Drug Therapy Codes: Enter the number of consecutive days shown in 24A.

Nursing Services: Enter the number of consecutive days shown in 24A.

RN Monitoring of Amphotericin B: Enter the number of 15-minute units of monitoring in excess of two hours on the date of service. Calculate the number of units as follows:

- **Step 1:** Total the amount of time that the RN is with the patient to monitor the administration of the drug on the date of service. (Do not include travel time or indirect time not spent with the beneficiary).
- Step 2: Subtract the two hours included in the per diem.
- Step 3: Divide the remaining number of minutes by 15 to get the number of whole units.
- **Step 4:** Add an additional unit if the remainder is 8 minutes or more. **Example:** The RN is with the beneficiary for 3 hours, 47 minutes on 11/15/04 to monitor the administration of Amphotericin B. The first two hours are included in the per diem rate and may not be billed. Divide the remaining one hour, forty-seven minutes (a total of 107 minutes) by 15. 107 minutes divided by 15 equals 7 units with a remainder of 2. Because the remainder is less than 8, do not add an

additional unit. Bill for 7 units for 11/15/04 under HCPCS code T1002SD.

Termination Allowance: Enter the number of days that the allowance applies, not to exceed seven days.

24H. EPSDT/FAMILY PLANNING:

Leave blank.

24I. EMG:

Leave blank.

24J. COB:

Optional.

24K. RESERVED FOR LOCAL USE:

Optional.